

Correction to the Drawings

As noted above, a proposed drawing change to comply with 37 C.F.R. § 1.84(p)(4) is submitted.

Overview of Daniels et al., Calderon et al. and Simpson et al. – Two Balloon Systems Are Not Capable of Fluid Exchange Distal to the Second (Most Distal) Balloon.

The three prior art references<sup>1</sup> used for the § 102 rejections, and the principal references in the § 103 rejections of all the pending claims are distinguishable by a clarification to the pending claims that emphasizes the capability of the present invention to enable fluid exchange distal of the occluder. Each of Daniels et al., Calderon, and Simpson et al. disclose a two-balloon system for isolating a portion of the vasculature for selective infusion and extraction of fluids, and for establishing an isolated circulation between the catheter system and the section of a vessel isolated by the two balloons. In these systems, as is apparent from Figure 6 of Daniels et al. (below) description of their intended use, the design of the apparatus employs the two balloons and various lumens and “ports” to exchange fluid in the isolated area between the two balloons to selectively treat these areas or to establish a desired fluid pathway located distally.

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<sup>1</sup> Paragraph 4 of the action is titled “Daniels et al.”, but the discussion appears pertinent to Simpson et al., USP 5,462,529. Applicants are assuming that the Simpson reference is asserted under Section 102 and are responding accordingly.

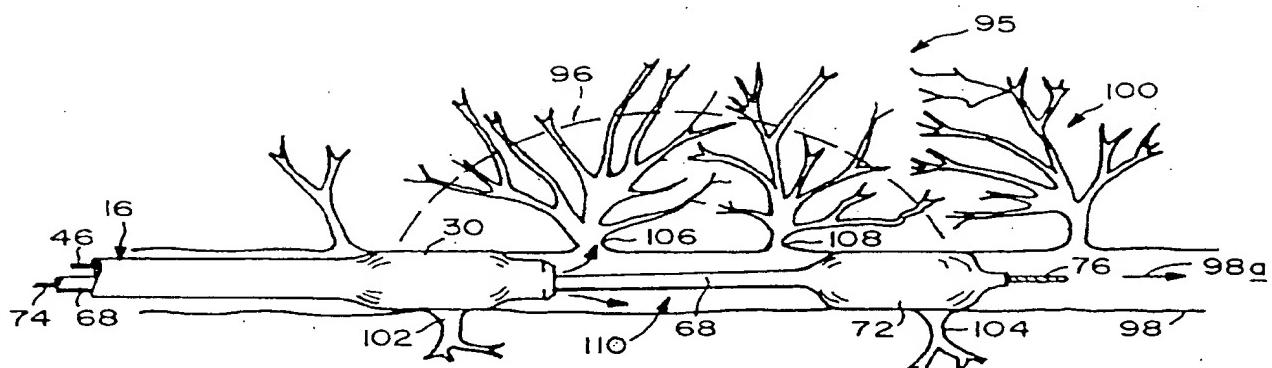


FIG. 6.

The abstract of Simpson et al. also describes the working promise of the design of these systems:

The device has inner and outer coaxial catheter members, each having an inflatable balloon attached near its distal end. When the balloons are inflated, a sealed treatment chamber is created between the balloons. The length of the treatment chamber is adjustable by sliding the coaxial catheter members with respect to each other to obtain a desired separation between the attached balloons before inflation. Biological debris is trapped within the chamber and removed by infusion and aspiration of a flushing fluid, reducing the risk of myocardial infarction.

While these systems have their advantages, the approach is fundamentally different from the present claimed invention. The fundamental design principle and the advantage offered by